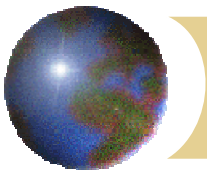


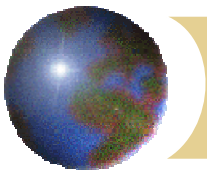
Managing WEEE RoHS and More

Stephen Greene
Medical Devices Workshop
June 21, 2005



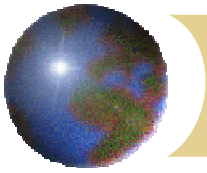
WEEE Man





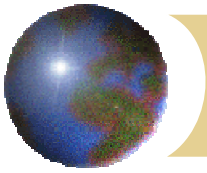
Existing and Pending EU Directives and Policies Germane to Products

DIRECTIVES	NUMBER	COMMENT
Batteries and Accumulators	91/62/EC	Proposed revisions are pending COM (2003) 723, current directive in effect
Packaging	94/157/EEC	Revised 2004/12/EC, current directive in effect.
RoHS (Restriction of Hazardous Substances)	2002/95/EC	Interpretations and exemptions pending. Effective July 1, 2006
WEEE (Waste Electronics and Electrical Equipment)	2002/96/EC	Amended 2003/108/EC. Effective August 13, 2005
End of Life Vehicles	2000/53/EC	In effect – automobiles only
Eco Label	Regulation EC No. 1980/2000	Voluntary. Environmental label of products
Integrated Product Policy	COM (2001) 68 final COM (2003) 302 final	Policy direction
REACH (Registration, Evaluation, and Authorization of Chemicals)	COM (2003) 644	Draft directive. Earliest possible date – 2007. Significant down stream impacts
EuP (Energy Using Products)	COM (2003) 453 final	Proposed Ecodesign for energy using products



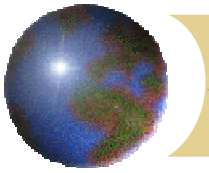
Agenda

- ⊕ The Product focus and your role
- ⊕ WEEE and RoHS is only the beginning
- ⊕ Design for the Environment
- ⊕ EuP and REACH
- ⊕ Thoughts on managing



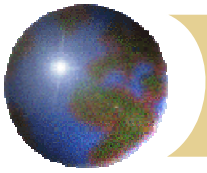
Cutting to the Chase.....

- ✚ This is not business as usual
- ✚ We are dealing with a new paradigm
- ✚ This is a new game with new rules and new team members
- ✚ You may be exempt but the likelihood is your supply chain is going to force you to RoHS compliance



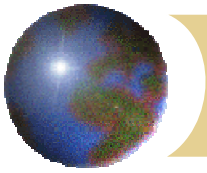
The Product Focus

- ⊕ You don't solve product design issues with an end of pipe device
- ⊕ The market place will enforce
- ⊕ Information is king
- ⊕ Success is managing information and orchestrating results among the players in your business
- ⊕ Don't forget your supply chain



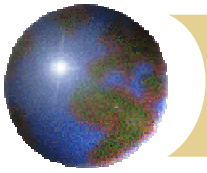
Why?

- ❖ The impact of the product is recognized
- ❖ The EU has become the de facto standard setter for product environmental regulations
- ❖ There is a paradigm shift from facility focused regulations
- ❖ The policy plan is to let the market internalize environmental costs



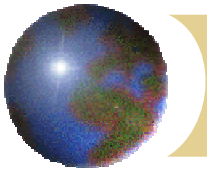
Changing How We Manage

- ✚ Traditional media specific regulations are still here and must be reckoned with
- ✚ Product impact and end of life issues have moved into the foreground
- ✚ The transition period will create risks and opportunities



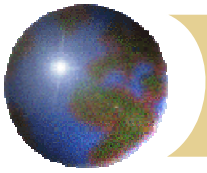
Extended Producer Responsibility

- ⊕ Simple concept that sounds good
- ⊕ Glosses over the complex reality of production and distribution
- ⊕ Forces you to understand your role
 - ⊠ Producer/manufacturer
 - ⊠ Importer
 - ⊠ Distance seller
- ⊕ Pay or design out the problem



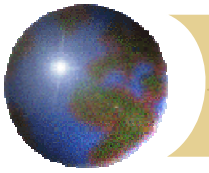
The Path Ahead For WEEE

- ✚ Which products?
- ✚ Providing the user with information
- ✚ Labeling and “putting on the market”
- ✚ Producer Registr’n (Who is the Producer)?
- ✚ Financial Obligation
- ✚ Product Design
- ✚ Recycle / Processing Information
- ✚ Paying your fees - administration



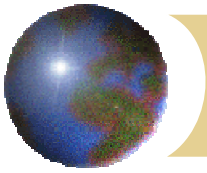
Deadlines

- ⊕ Backup to see how much time you have
- ⊕ No changes in the RoHS July 1, 2006
- ⊕ Exemptions are in a bit of political turmoil but not likely to drop
- ⊕ WEEE implementation is all over the place
- ⊕ Don't get distracted with the slow countries
- ⊕ Get the Crossed out Wheelie mark in place – Still August 13, 2005



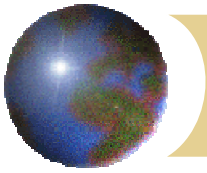
RoHS

- ⊕ Verify what your suppliers are claiming
- ⊕ Inventory
 - ⊞ Flushing and lot dating
 - ⊞ Avoiding cross contamination in production
- ⊕ Part Numbering
- ⊕ Contract manufacturing and cost of new tools



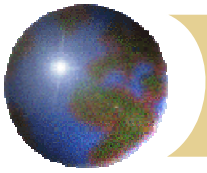
Documentation

- ✚ Balance the cost of validation with the risk to your business
- ✚ Wink and a nod is the quickest and easiest route to disaster.
- ✚ Develop a technical file that can be paper but preferably searchable electronic
- ✚ Build into change management and ECOs (engineering change orders)



WEEE

- ❖ Unlike RoHS, this starts but doesn't stop
- ❖ You will pay for the product you put on the market
- ❖ It is the individual item and not when the product line was started.
- ❖ Marking with the Crossed Out Wheelie bin starts August 13, 2005 for products put on the market



WEEE Marking

- ✚ For Products
- ✚ Accessories may warrant marking if they are sold separately
- ✚ There are size and durability requirements
- ✚ The Commission and CENELEC are at odds so lean towards the commission
- ✚ If too small, mark the packaging, instructions and warrantee

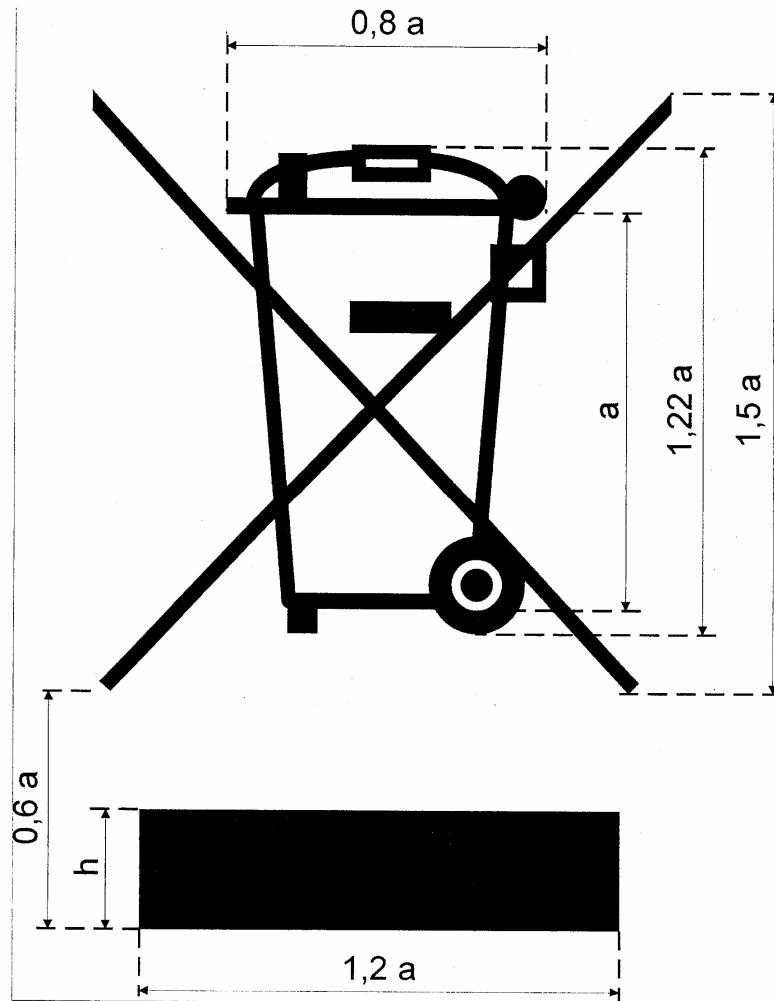
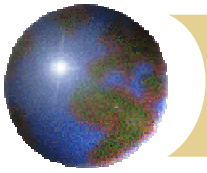


Figure 1 – Marking of electrical and electronic equipment as required by 4.1 b) 2)

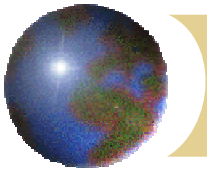
NOTE 1 The symbol of the crossed out wheeled bin and the dimensional relationship are the same as required for batteries and defined in Figure 2 of EN 61429/A11.

When using the marking in Figure 1 modifications caused by production limitations and variations (e.g. modifying of line thickness, rounding of corners, matching of lines) are permitted provided the visual appearance is maintained.



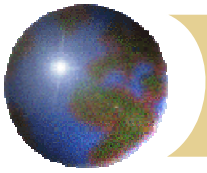
WEEE Responsibilities

- ❖ Who is the producer?
- ❖ Do you have a legal presence in the country when the EEE is sold?
- ❖ Who are you customers? Households? Commercial? Both?
- ❖ Producer Registration includes a fee
- ❖ Take back – your own program or you join a scheme



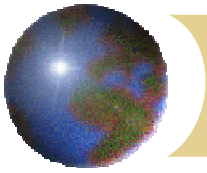
Producer Registration

- ✚ Each country has a registration authority
- ✚ Level of information varies
- ✚ There will be fees to offset the administrative cost
- ✚ Typical minimum information
 - ▣ Brand Name and product
 - ▣ Company Name
 - ▣ Contact person and office



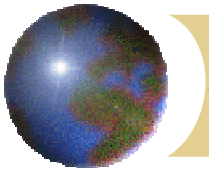
Producer Registration con't

- ✚ Seems innocent enough??
- ✚ There will be a central register in each country
- ✚ There will be communication among counties of problems
- ✚ It will be very easy to see if the Brand Name and product are free riding on other directives such as batteries and packaging



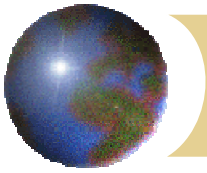
RoHS and WEEE Caveats

- ⊕ This is a long-term issues
- ⊕ Design to reduce costs
- ⊕ What is your competition doing?
- ⊕ Have you over looked packaging and batteries?
- ⊕ Create systems which will anticipate EuP and REACH requirements



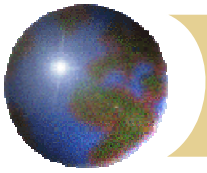
RoHS and REACH

- ✚ RoHS is the first step in material restrictions
- ✚ 6 (maybe 7, if deca is added) chemicals
- ✚ RoHS is Product oriented
- ✚ REACH can be both. You need to understand the exposure
- ✚ REACH will really be a small volume “downstream user” concern



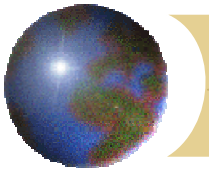
EuP, REACH and WEEE

- ✚ Energy using Products that have stand by power cubes, have a CE mark and have motors
- ✚ Energy consumption is a growing concern
- ✚ Do you use special chemicals? Do they have health or safety concerns?
- ✚ Think Design for the Environment and life cycle assessment



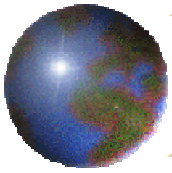
WEEE Countries

- ✚ Actual, there are WEEE requirements for certain products (CRTs, TVs and Displays) in California and other US states
- ✚ All 25 EU countries and a few European countries, Switzerland and Norway
- ✚ South Korea, Japan, Taiwan
- ✚ Canadian Provinces
- ✚ Pending in China



A Plan Forward

- ❖ The WEEE Roadmap
- ❖ Information Service
- ❖ Consulting
- ❖ Positioning your company for EuP and REACH



Question and Answers

 **Thank You**